



Helping drug safety reviewers proactively and effectively manage risk

Qinecsa Quantitative Signal Detection as a Service (QSDaaS)

FIT-FOR-PURPOSE SIGNAL DETECTION & SIGNAL MANAGEMENT CAPABILITIES

Qinecsa Quantitative Signal Detection Services

supports drug safety reviewers with the detection of safety signals from the FDA Adverse Event Reporting System (FAERS).

Qinecsa Quantitative Signal Detection Services, paired with the Qinecsa team's experience and expertise helps smaller safety groups proactively and effectively manage risk.



The Latest FAERS & VigiBase Data



Organized MedDRA Term Scores



Collaboration with Signal Detection & Signal Management Experts



Scheduled Data Mining Reports



Clear Results Displayed in PDF & Excel



Proven Statistical Methods
like PRR, TTO and OE

Adopt the Qinecsa Quantitative Signal Detection Services

REDUCED COSTS

Access to industry-standard signal detection techniques and experts without the costs of internal expertise and infrastructure.

EASY STARTUP

Fit-for-purpose analysis and output designed by signal detection experts to achieve regulatory compliance.

TRANSPARENT PROCESS

Intermediate analysis results available for review and auditing.

RELIABLE RESULTS

Validated reports designed and delivered by safety industry leaders.

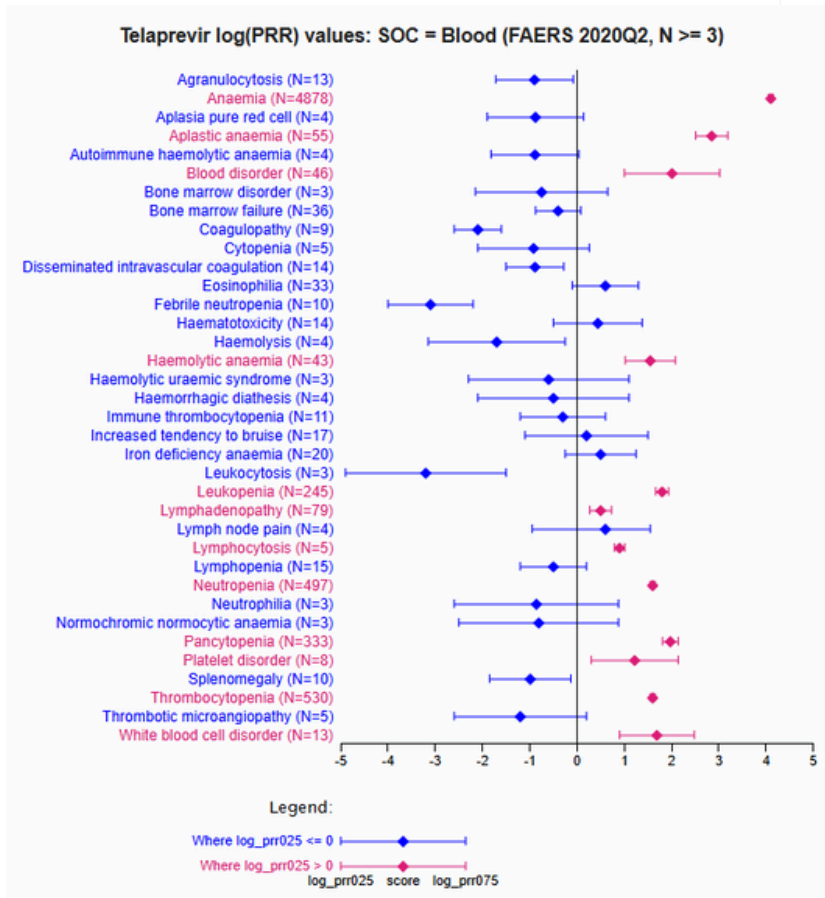
ASSISTANCE IN INTERPRETING RESULTS

Subject-matter experts and data scientists help you interpret data mining results.

Proven Statistical Methods

The statistical methods and data visualization techniques have been developed in collaboration with safety scientists in regulatory and sponsor organizations in the USA, Europe and Australia.

Log PRR signal scores for Levofloxacin —
Hepatocellular damage & hepatitis:



Example forest plot graphical display of PRR signal scores for a therapy and event combination available in QSD Reports.

Clean Data & Reliable Results

It's critical for safety reviewers to have confidence that the adverse event data provides accurate and reliable results. Qinecsa's extensive experience in cleaning spontaneous report data for optimized data mining includes:

- ✓ Mapping adverse event reports to a consistent event terminology.
- ✓ Drug name harmonization, cleaning verbatim drug names, and mapping trade and generic names.
- ✓ Quality assurance of the updated data prior to release for use.
- ✓ Utilizing recognized disproportionality methods like Proportional Reporting Ratio, Time to Onset, and Observed over Expected analysis.

Ready to Get Started?

Visit qinecsa.com or reach out to contact@qinecsa.com for a demonstration.

Qinecsa

Specialists in technology-led pharmacovigilance solutions.

